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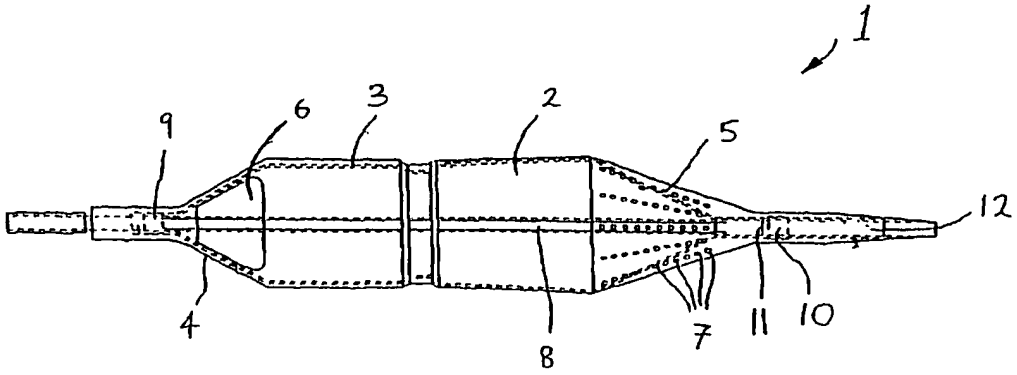
(54) Title: A MEDICAL DEVICE



(57) Abstract: A support (3) for an embolic protection filter comprises a support element in the form of one or more wires (20) of superelastic material, such as Nitinol. A core of radiopaque material is embedded within at least portion of at least one of the support wires (20). The core may be in the form of a wire (21) of a suitable radiopaque material, such as gold, or platinum, or mercury and extends along the length of a support wire. The radiopaque wire (21) is located substantially along the neutral axis of bending of the support wire (20). The radiopaque wire (21) provides visualisation for a clinician during transport of the filter (1) through a vasculature and deployment of the filter (1) in the vasculature.

WO 03/088805 A2

"A medical device"

Introduction

This invention relates to a medical device for transport through a body passageway and deployment in a body, in particular it relates to an intravascular medical device, such as an embolic protection filter.

It is known to use a coating of a radiopaque material on an embolic protection filter to achieve visualisation of the filter during transport and deployment of the filter in a vasculature. However radiopaque materials have a limited range of elastic deformation. Thus it is generally necessary to plastically deform the radiopaque material to achieve deployment of the filter. This plastic deformation increases the forces required to facilitate deployment of the filter and in this way has a dampening effect on the overall system.

This invention is aimed at overcoming at least some of the problems associated with radiopaque dampening.

Statements of Invention

According to the invention, there is provided a medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a radiopaque core.

The second moment of area of the radiopaque material is proportional to the fourth power of its diameter. Therefore because the radiopaque material is provided as the core of the support, this greatly reduces the diameter and thus the second moment of area of the radiopaque material. Correspondingly the forces required to facilitate deployment of the medical device are also greatly reduced.

In this manner the invention minimises the dampening effect of the radiopaque material on the medical device.

By locating the radiopaque material as the core of the support, this also results in a low-profile medical device.

In one embodiment of the invention the core is located substantially along the neutral axis of bending of the support.

Preferably the support comprises at least one support element. The support element may be of a superelastic material. Ideally the radiopaque core is provided as a core embedded within at least one support element. In one case the radiopaque core is in powder form. In another case the radiopaque core is in liquid form.

In a preferred embodiment the radiopaque core comprises a radiopaque element amongst a plurality of support elements. The element may comprise a wire. Ideally the elements are wound together.

The radiopaque core may be of mercury, or gold, or platinum.

In another aspect, the invention provides a medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a reservoir enclosing a fluid, the fluid being expandable upon an increase in temperature to bias the support to the expanded configuration.

According to a further aspect of the invention, there is provided a medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a reservoir enclosing a fluid, the fluid being pressurised to bias the support to the expanded configuration upon release of a constraint.

In one case the reservoir comprises an enclosed tube. The tube may extend at least partially circumferentially around the device. Ideally the ends of the tube meet to form an enclosed loop.

The fluid may be of a radiopaque material. Preferably the fluid is liquid mercury.

In a preferred embodiment of the invention the device is an intravascular medical device for transport through a vasculature and deployment in a vasculature. Most preferably the device is an embolic protection filter. Ideally the filter comprises a filter body supported by the support, the filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, and the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: –

Fig. 1 is a side view of a medical device according to the invention;

Fig. 2 is a partially cut-away, perspective view of a support and a radiopaque core of the medical device of Fig. 1;

Figs. 3 and 4 are partially cut-away, perspective views of a support and a radiopaque core of other medical devices according to the invention;

Figs. 5 to 7 are perspective views illustrating deployment of another medical device according to the invention; and

Fig. 8 is a partially cut-away, perspective view of a support of the medical device of Figs. 5 to 7.

Detailed Description

Referring to the drawings, and initially to Figs. 1 and 2 thereof, there is illustrated a medical device according to the invention. In this case, the medical device is an embolic protection filter 1 which has a collapsed configuration for transport through a vasculature, and an expanded configuration (Fig. 1) for deployment in a vasculature to filter undesired embolic material from the bloodstream flowing through the vasculature.

The filter 1 comprises a filter body 2 supported by a filter support 3. The filter support 3 is in this case mounted around an inner tube 8. The proximal end 9 of the filter support 3 is fixed to the inner tube 8, and the distal end 10 of the filter support 3 is fixed to a sleeve 11 which is slidable over the inner tube 8, so that the filter 1 is movable from the collapsed configuration to the expanded configuration to support the filter body 2 in the expanded configuration, as illustrated in Fig. 1.

As illustrated in Fig. 2, the support 3 comprises a support element, in this case in the form of one or more wires 20 of superelastic material, such as Nitinol. A core of radiopaque material is embedded within at least portion of at least one of the support wires 20. In this case, the core is also in the form of a wire 21 of a suitable radiopaque material, such as gold, or platinum, or mercury and extends along the length of a support wire.

The radiopaque wire 21 is located substantially along the neutral axis of bending of the support wire 20.

The radiopaque wire 21 provides visualisation for a clinician during transport of the filter 1 through a vasculature and deployment of the filter 1 in the vasculature.

By providing the radiopaque wire 21 as the core of the support wire 20, this minimises the diameter of the radiopaque wire 21. Because the second moment of area of the radiopaque wire 21 is proportional to the fourth power of its diameter, the second moment of area of the radiopaque wire 21 is also minimised. Correspondingly, the forces required to plastically deform the radiopaque wire 21 as the support wire 20 moves from the collapsed configuration to the expanded configuration, upon deployment of the filter 1, are also minimised.

In this manner, the radiopaque core configuration of the invention acts to minimise the dampening effect of the radiopaque material, which is necessary to achieve visualisation of the filter 1.

The filter body 2 has an inlet end 4 and an outlet end 5. The inlet end 4 has one or more, and in this case two, large inlet openings 6 which are sized to allow blood and embolic material enter the filter body 2. The outlet end 5 has a plurality of small outlet openings 7 which are sized to allow through passage of blood but to retain undesired embolic material within the filter body 2. In this way, the filter 1 captures and safely retains any undesired embolic material in the blood stream within the filter body 2 while facilitating continued flow of blood through the vascular system. Emboli are thus prevented from flowing further downstream through the vascular system, which could otherwise have potentially catastrophic results.

In the expanded configuration, the filter body 2 is supported by the filter support 3 so as to maximise the internal volume of the filter body 2 to capture and safely retain as much embolic material as possible.

The filter body 2 may be of an oriented polymeric material, as described in International patent application No. PCT/IE01/00087, the relevant contents of which are incorporated herein by reference.

The inner tube 8 has a guidewire lumen 12 therethrough for passing the filter 1 over a guidewire.

In use, a guidewire is introduced into and advanced through a vasculature until the guidewire crosses a desired treatment location. A delivery catheter is then used to deliver the embolic protection filter 1 through the vasculature over the guidewire, the filter 1 being housed within a distal pod of the delivery catheter in the collapsed configuration.

The filter 1 may, in one case, be loaded into a delivery catheter as described in International patent applications Nos. PCT/IE01/00052 and PCT/IE01/00053, the relevant contents of which are incorporated herein by reference.

When the distal pod has been advanced to a desired site distal to the treatment location, the pod is moved proximally relative to an inner pusher to deploy the filter 1 out of the pod into the expanded configuration, as described in further detail in International patent applications Nos. PCT/IE01/00052 and PCT/IE01/00053. After complete deployment of the filter 1, the delivery catheter is withdrawn from the vasculature.

An interventional procedure is then carried out at the treatment location. A range of procedures are possible such as a stenting procedure using a self-expanding stent, a balloon angioplasty procedure, a balloon-expandable stenting procedure, an atherectomy procedure, a lysis. Any embolic material generated during the interventional procedure is captured and safely retained in the deployed filter 1. After completion of the interventional procedure, a retrieval catheter is introduced into the vasculature, and advanced through the vasculature until the treatment location has been crossed. The filter 1 is then collapsed and retrieved into the retrieval catheter and with it the captured embolic material. When the filter 1 has been fully collapsed and retrieved into the retrieval catheter, the retrieval catheter

with the collapsed filter 1 and retained emboli therein are withdrawn from the vasculature. In this way, the filter 1 may be used to capture and safely remove any embolic material which has been generated during the interventional procedure.

The radiopaque material may also be provided in powder form 25, as illustrated in Fig. 3, or in liquid form 26, as illustrated in Fig. 4. Because the radiopaque core 25, 26 is embedded within the support wire 20, the radiopaque powder 25 or radiopaque liquid 26 will be safely retained and controlled within the support wire 20.

By using a powder or liquid for the radiopaque material, the yield stress of the radiopaque material is reduced. Thus the forces required to move the support wire 20 from the collapsed configuration to the expanded configuration are further reduced.

In another embodiment of the invention, the support may comprise a plurality of support elements. One or more of the support elements may have a radiopaque core embedded within the support element.

In addition, the support elements may be wound together in a braid or pleat.

In a further embodiment, the radiopaque core may be provided as a radiopaque element, such as a radiopaque wire, amongst a plurality of support elements, such as support wires. The radiopaque wire is located towards the centre of the bundle of support wires which are wound or braided together.

Referring to Figs. 5 to 8 there is illustrated another embolic protection filter 30 according to the invention, which is similar to the embolic protection filter 1 of Figs. 1 and 2, and similar elements in Figs. 5 to 8 are assigned the same reference numerals.

In this case, the distal end 10 of the filter support 3 is fixed to the sleeve 11, and the proximal end 9 of the filter support 3 is unconnected to the inner tube 8. The filter body 2 has a single, large inlet opening 31 at the inlet end 4 to allow blood flow into the filter 30.

The support 3 comprises a reservoir for enclosing a fluid, the reservoir being provided, in this case, by a tube 32 which extends circumferentially around the filter 30 at the inlet end 4 to form an enclosed loop around the inlet opening 31, as illustrated in Fig. 6.

The tube 32 encloses a fluid 33, in this case mercury. The temperature of the fluid 33 increases towards body temperature upon deployment of the filter 30 in a vasculature (Fig. 5), which causes the fluid 33 to expand. This expansion of the fluid 33 forces the support tube 32 towards the expanded configuration (Fig. 6), until the support tube 32 is fully expanded and the filter 30 is supported in the expanded configuration (Fig. 7).

It will be appreciated that the expansile fluid 33 may be of any suitable material. By using a radiopaque material, such as mercury, this provides the additional advantage that visualisation of the filter will be possible during transport of the filter through a vasculature and deployment of the filter in a vasculature.

In another embolic protection filter according to the invention, the fluid enclosed in the reservoir may be pressurised. In this case, upon release of a constraint on the filter, such as upon deployment of the filter out of the pod of the delivery catheter, the pressurised fluid in the support reservoir forces the support towards the expanded configuration until the filter is supported in the fully expanded configuration.

It will be appreciated that the fluid may be provided by a liquid or a gas. If a radiopaque fluid is used, visualisation of the filter will also be possible.

It will be appreciated that the radiopaque core aspect of the invention, and/or the temperature expansile fluid aspect of the invention, and/or the pressurised fluid aspect of the invention may be used in any suitable manner or combination with any appropriate medical device.

It will further be appreciated that these aspects of the invention may be applied with any medical device for transport through a body passageway and deployment in a body.

The invention is not limited to the embodiments hereinbefore described, with reference to the accompanying drawings, which may be varied in construction and detail.

Claims

1. A medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a radiopaque core.

2. A device as claimed in claim 1 wherein the core is located substantially along the neutral axis of bending of the support.

3. A device as claimed in claim 1 or 2 wherein the support comprises at least one support element.

4. A device as claimed in claim 3 wherein the support element is of a superelastic material.

5. A device as claimed in claim 3 or 4 wherein the radiopaque core is provided as a core embedded within at least one support element.

6. A device as claimed in claim 5 wherein the radiopaque core is in powder form.

7. A device as claimed in claim 5 wherein the radiopaque core is in liquid form.

8. A device as claimed in claim 3 or 4 wherein the radiopaque core comprises a radiopaque element amongst a plurality of support elements.

9. A device as claimed in any of claims 3 to 8 wherein the element comprises a wire.

10. A device as claimed in any of claims 3 to 9 wherein the elements are wound together.

11. A device as claimed in any preceding claim wherein the radiopaque core is of mercury, or gold, or platinum.

12. A medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a reservoir enclosing a fluid, the fluid being expandable upon an increase in temperature to bias the support to the expanded configuration.

13. A medical device having a collapsed configuration for transport through a body passageway, and an expanded configuration for deployment in a body;

the medical device comprising a support movable from the collapsed configuration to the expanded configuration to support the medical device in the expanded configuration;

the support comprising a reservoir enclosing a fluid, the fluid being pressurised to bias the support to the expanded configuration upon release of a constraint.

14. A device as claimed in claim 12 or 13 wherein the reservoir comprises an enclosed tube.

15. A device as claimed in claim 14 wherein the tube extends at least partially circumferentially around the device.

16. A device as claimed in claim 15 wherein the ends of the tube meet to form an enclosed loop.

17. A device as claimed in any of claims 12 to 16 wherein the fluid is of a radiopaque material.

18. A device as claimed in claim 17 wherein the fluid is liquid mercury.

19. A device as claimed in any preceding claim wherein the device is an intravascular medical device for transport through a vasculature and deployment in a vasculature.

20. A device as claimed in claim 19 wherein the device is an embolic protection filter.

21. A device as claimed in claim 20 wherein the filter comprises a filter body supported by the support, the filter body having an inlet end and an outlet end, the inlet end of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body, and the outlet end of the filter body having a plurality of outlet openings sized to allow through passage of blood but to retain undesired embolic material within the filter body.

22. A medical device substantially as hereinbefore described with reference to the accompanying drawings.

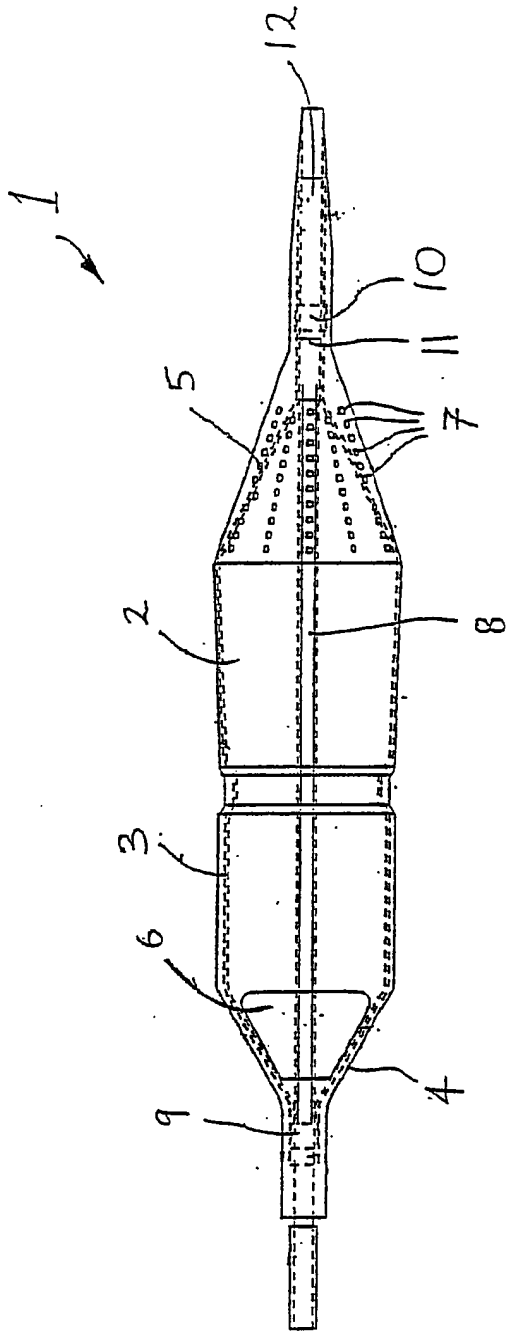


FIG. 1

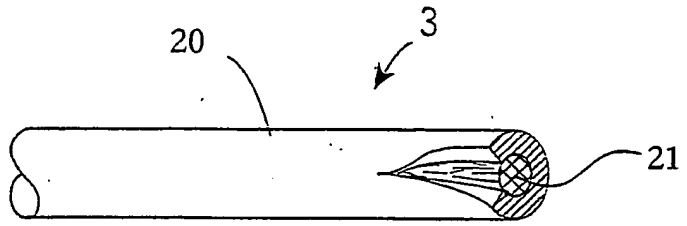


FIG. 2

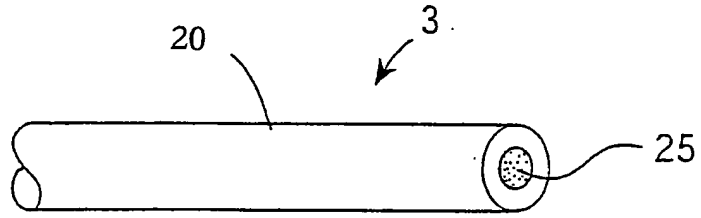


FIG. 3

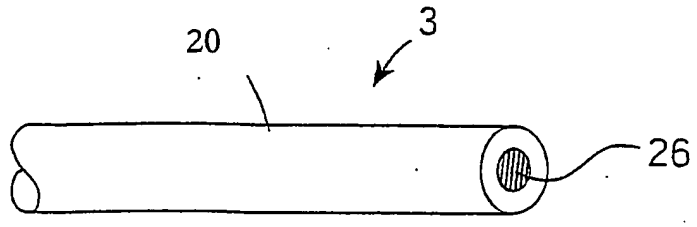


FIG. 4

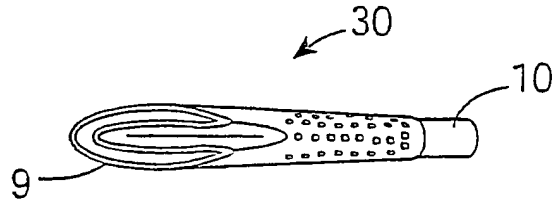


FIG. 5

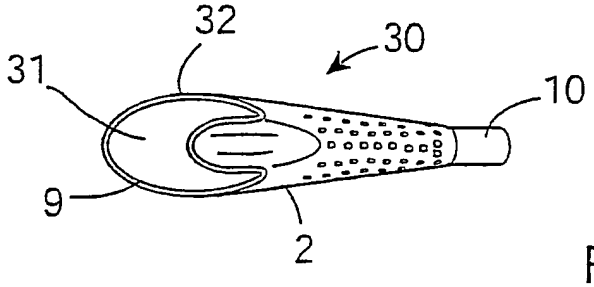


FIG. 6

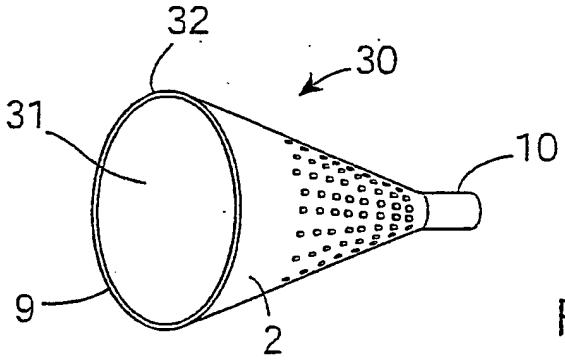


FIG. 7

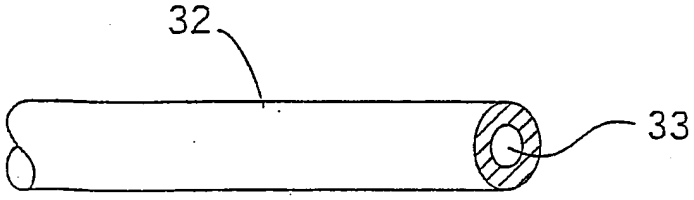


FIG. 8